UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/792,376	03/04/2004	Vladimir Sabetsky	T63774 1010.1	3029

26158 7590 05/06/2011

WOMBLE CARLYLE SANDRIDGE & RICE, PLLC
ATTN: IP DOCKETING
P.O. BOX 7037
ATLANTA, GA 30357-0037

EXAMINER	
NIEBAUER, RONALD T	
ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
05/06/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/792,376	**Applicant(s)** SABETSKY, VLADIMIR	
	Examiner RONALD NIEBAUER	**Art Unit** 1654	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 25 April 2011 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *6* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *25 April 2011*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *27-37,41 and 43-51*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/CECILIA J TSANG/
Supervisory Patent Examiner, Art Unit 1654

/Ronald T Niebauer/
Examiner, Art Unit 1654

Continuation of 11. does NOT place the application in condition for allowance because: No claims have been amended. All of the rejections as set forth on 10/25/10 are maintained. Further, the reply to the arguments as set forth previously remain of record. All of applicants arguments have been considered but are not found persuasive.

With respect to the 112 2nd rejection applicants argue that paragraph 0070 provides examples and applicants have not tried to redefine the term.
Applicants argue that the claims are to be given the broadest possible meaning and that the term 'recombinant' is used in a manner consistent with the ordinary and customary meaning.
Applicants argue that an office action refers to a structure of insulin thus one would have an understanding of the claims.

Although applicants argue that paragraph 0070 provides examples and applicants have not tried to redefine the term, it is first noted that applicants reply dated 8/10/10 page 7 first complete paragraph states that the specification provides a definition of recombinant. Thus there is a reasonable basis that section 0070 provides a definition. Although applicants assert that section 0070 only includes examples, such section does not include the word 'example'. In fact, section 0070 includes the word recombinant in quotations which is commonly used to define a term. There is no other reason to include the word recombinant in quotations. It is noted that section 0068 refers to a word in quotations are refers to 'defined'. Thus it is consistent with applicants own specification, applicants own arguments (see 8/10/10 page 7 first complete paragraph) and the standard in the art to interpret 'The term "recombinant" refers to…' as a definition. Thus applicants have provided a definition.
Although applicants argue that the claims are to be given the broadest possible meaning and that the term 'recombinant' is used in a manner consistent with the ordinary and customary meaning, applicants have provided no evidence that 'recombinant insulin' is recognized as a combinatorial library of molecules which may be further processed into another state (see section 0070 of applicants specification). Further, MPEP 2106 expressly states: "Where an explicit definition is provided by the applicant for a term, that definition will control interpretation of the term as it is used in the claim. Toro Co. v. White Consolidated Industries Inc., 199 F.3d 1295, 1301, 53 USPQ2d 1065, 1069 (Fed. Cir. 1999) (meaning of words used in a claim is not construed in a "lexicographic vacuum, but in the context of the specification and drawings."). Thus the explicit definition of 'recombinant' controls interpretation.
Although Applicants argue that an office action refers to a structure of insulin thus one would have an understanding of the claims, such reference is to insulin as taught by Schroder. Schroder does not recite that the insulin is recombinant where recombinant refers to a combinatorial library of molecules which may be further processed into another state. A discussion of the scope and clarity of a claim is separate and distinct from addressing how the claim limtations are met. In the instant case, the office provides evidence about insulin (see previous office action - Schroder teach insulin, The Medline entry for the Schroder article lists the number 11061-68-0 as the registry number of the insulin (last line), The registry entry for 11061-68-0 recites that the name is human insulin (line 3). As such, Schroder teach human insulin) while applicants continue to make unsubstanitated assertions.

With respect ot the 102 rejection via Schroder (Methods in Enzymnology 1985), applicants argue that MPEP 2112(V) states that reasoning or evidence tending to show inherency is necessary and the examiner has not shown how the prior art include the recited properties.
Applicants argue that the examiner improperly imports information from the specification with respect to the word 'shell'.
Applicants argue tha the Lengsfeld reference is not relevant and is not prior art.
Applicants argue that Schroder teaches away.
Applicants argue that Schroder shows schematic views and there is nothing to show that it is realistic.
Applicants argue that MPEP 2113 sidesteps the issue.
Although applicants argue that MPEP 2112(V) states that reasoning or evidence tending to show inherency is necessary and the examiner has not shown how the prior art include the recited properties, in the instant case, the prior art teach the same components, insulin and crystallized dextran, as in the instant claims. The fact that the claimed components are the same is adequate reasoning to show inherency. Further, since the Office does not have the facilities for examining and comparing Applicants' composition with the composition of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald, 619 F.2d 67, 205 USPQ 594 (CCPA 1980), and "as a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." In re Brown, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972). In the instant case, the claim product and prior art product are substantially identical in composition (i.e. comprise crystallized dextran and insulin) so a prima facie case of anticipation has been established (see MPEP section 2112.01 I). Although applicants argue about claimed properties, MPEP 2112.01 I states that: Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established.Although applicants assert that In re Best and In re Fitzgerald are 'BIOLERPLATE LANGUAGE", such fact patterns are relevant to the instant case (see MPEP 2112.01 I)..
Although Applicants argue that the examiner improperly imports information from the specification with respect to the word 'shell', it is noted that claim 43 recites 'insulin is encapsulated'. The specification (section 0073) states that for a therapeutic agent to not be encapsulated that the microparticle does not act as a shell (it is noted that 'i.e.' means 'that is'). Since MPEP section 2111 states that claims are to be interpreted consistent with the specification one would interpret as expressly recited in section 0073. The interpretation is consistent with the specification.
Although Applicants argue tha the Lengsfeld reference is not relevant and is not prior art, MPEP 2124 states that universal facts need not be available as prior art. Further, Lengsfeld is not used in the rejection. It is cited to show that the offices interpretations are consistent with the prior art. Instead of making unsubstantiated assertions, evidence is provided. It is noted that the Lengsfeld definition of encapsulation is consistent with applicants definition (section 0073) as both refer to a shell.
Although Applicants argue that Schroder teaches away, MPEP 2131.05 states: A reference is no less anticipatory if, after disclosing the invention, the reference then disparages it. The question whether a reference "teaches away" from the invention is

inapplicable to an anticipation analysis. Celeritas Technologies Ltd. v. Rockwell International Corp., 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir. 1998).
Although Applicants argue that Schroder shows schematic views and there is nothing to show that it is realistic, MPEP 2125 recites that drawings can be used as prior art and must be evaluated for what they disclose and suggest. In the instant case,the prior art teach the same components, insulin and crystallized dextran, as in the instant claims. The fact that the claimed components are the same is adequate reasoning to show inherency. Further, the drawings provide further evidence that the claim limitations are met. It appears that applicants argue that conclusions can not be drawn from schematics then applicants go ahead and conclude that insulin is completely within the dextran. Such argument is contradictory.
Although applicants argue that MPEP 2113 sidesteps the issue, in the reply dated 8/10/10 pages 12-13 applicants refer to methods of preparing compositions. It is unclear how addressing applicants arguments is sidestepping the issue (unless the arguments themselves ar not relevant). In the instant case, the office does not have the facility to test and compare the prior art product and the claimed product. There is no evidence of record to establish a difference between the products. However, as set forth in the rejection there is a reasonable basis that the claim limitations are met.
Since applicants have provided no arguments with respect to Schroder (US 4713249) (arguments are only to Schroder (Methods in Enzymology, 1985 (see page 8) the rejection via Schroder (US 4713249) is maintained for reasons of record.

With respect to the 103 rejections applicants argue that Schroder does not teach the invention as claimed and the secondary references do not cure the deficiency.
Although applicants argue that Schroder does not teach the invention as claimed and the secondary references do not cure the deficiency, in the instant case, the prior art teach the same components, insulin and crystallized dextran, as in the instant claims. The fact that the claimed components are the same is adequate reasoning to show inherency. Further, since the Office does not have the facilities for examining and comparing Applicants' composition with the composition of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald, 619 F.2d 67, 205 USPQ 594 (CCPA 1980), and "as a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." In re Brown, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972). In the instant case, the claim product and prior art product are substantially identical in composition (i.e. comprise crystallized dextran and insulin) so a prima facie case of anticipation has been established (see MPEP section 2112.01 I). Although applicants argue about claimed properties, MPEP 2112.01 I states that: Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established.